

CLAIMS

1. A method of identifying or selecting a patient having an elevated EphA2 level in a tumor tissue, comprising measuring EphA2 level in a tumor tissue of a patient, and selecting a patient having an elevated EphA2 level in the tumor tissue.
2. The method of claim 1, wherein the step of measuring EphA2 level in a tumor tissue of a patient comprises using an EphA2 immunohistochemistry (IHC) staining assay.
3. A method of identifying or selecting a patient having an elevated EphA2 level in a tumor tissue, comprising measuring staining intensity in a tumor tissue section of a patient using an EphA2 IHC staining assay, and selecting a patient who is staining positive in the EphA2 IHC staining assay.
4. The method of any one of claims 1-3, wherein the patient has pancreatic cancer, stomach cancer, bladder cancer, head & neck cancer, non-small cell lung cancer (NSCLC), triple negative breast cancer (TNBC), or ovarian cancer.
5. The method of claim 2 or 3, wherein the EphA2 immunohistochemistry (IHC) staining assay uses a human EphA2 antibody selectively binding to the extracellular domain (ECD) or cytoplasm domain of EphA2.
6. The method of claim 5, wherein the human EphA2 antibody selectively binding to the extracellular domain (ECD) of EphA2 is human EphA2 antibody AF3035.
7. The method of claim 3, wherein staining positive in the EphA2 IHC staining assay refers to an H-score of about 15 or more, about 20 or more, about 30 or more, about 40 or more, about 50 or more, about 75 or more, about 100 or more, about 125 or more, or about 150 or more in a tumor tissue section in the EphA2 IHC staining assay.
8. The method of claim 3, wherein staining positive in the EphA2 IHC staining assay refers to an H-score for tumor cell membrane of about 15 or more, about 20 or more, about 30 or more, about 40 or more, about 50 or more, about 75 or more, about 100 or more, about 125 or more, or about 150 or more in a tumor tissue section in the EphA2 IHC staining assay.
9. The method of claim 3, wherein staining positive in the EphA2 IHC staining assay refers to an H-score for tumor cell cytoplasm of about 15 or more, about 20 or more, about 30 or more, about 40 or more, about 50 or more, about 75 or more, about 100 or more, about 125 or more, or about 150 or more in a tumor tissue section in the EphA2 IHC staining assay.
10. Use of a Bicycle toxin conjugate specific for EphA2, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition thereof in the manufacture of a medicament for treating a cancer in a patient having an elevated EphA2 level in a tumor tissue.
11. The use of claim 10, wherein a patient having an elevated EphA2 level in a tumor tissue refers to a patient having an H-score of about 15 or more, about 20 or more, about 30 or more, about 40 or more, about 50 or more, about 75 or more, about 100 or more, about 125 or more, or about 150 or more in a tumor tissue section in an EphA2 IHC staining assay.

12. Use of a Bicycle toxin conjugate specific for EphA2, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition thereof in the manufacture of a medicament for treating a cancer in a patient, wherein the patient has an H-score of about 15 or more, about 20 or more, about 30 or more, about 40 or more, about 50 or more, about 75 or more, about 100 or more, about 125 or more, or about 150 or more in a tumor tissue section in an EphA2 IHC staining assay.
13. The use of any one of claims 10-12, wherein a cancer is pancreatic cancer, stomach cancer, bladder cancer, head & neck cancer, non-small cell lung cancer (NSCLC), triple negative breast cancer (TNBC), or ovarian cancer.
14. The use of claim 11 or 12, wherein the EphA2 IHC staining assay uses a human EphA2 antibody selectively binding to the extracellular domain (ECD) or cytoplasm domain of EphA2.
15. The use of claim 14, wherein the human EphA2 antibody selectively binding to the extracellular domain (ECD) of EphA2 is human EphA2 antibody AF3035.
16. The use of claim 12, wherein the H-score refers to an H-score for tumor cell membrane or an H-score for tumor cell cytoplasm.
17. Use of BT5528, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition thereof in the manufacture of a medicament for treating a cancer in a patient, wherein the patient has an H-score for tumor cell membrane of about 15 or more, about 20 or more, about 30 or more, about 40 or more, about 50 or more, about 75 or more, about 100 or more, about 125 or more, or about 150 or more in a tumor tissue section in an EphA2 IHC staining assay.
18. The use of claim 17, wherein a cancer is pancreatic cancer, stomach cancer, bladder cancer, head & neck cancer, non-small cell lung cancer (NSCLC), triple negative breast cancer (TNBC), or ovarian cancer.
19. The use of claim 17, wherein the EphA2 IHC staining assay uses a human EphA2 antibody selectively binding to the extracellular domain (ECD).
20. The use of claim 19, wherein the human EphA2 antibody selectively binding to the extracellular domain (ECD) of EphA2 is human EphA2 antibody AF3035.